product was refused entry on April 5, 2021.

On or about March 17, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Newark IMF and which was addressed to him. FDA determined that the product contained in this parcel was 364 tablets of BEGMA–100 Sildenafil Citrate Tablets 100 MG and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on April 23, 2021.

On or about March 24, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 870 tablets of sildenafil citrate and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol ''Rx only'' on its label. The product was refused entry on April 19, 2021.

On or about April 20, 2021, Mr. Hampton-Bey II offered for import a parcel intercepted and processed by FDA at the Chicago IMF and which was addressed to him. FDA determined that the product contained in this parcel was 800 tablets of Sildenafil 100 MG Tablets and was a misbranded drug because the article was determined to be a drug that was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on May 11, 2021.

As a result of this pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Mr. Hampton-Bey II, by certified mail on April 4, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Hampton-Bey II's pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Hampton-Bey II of the proposed debarment and offered him an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Hampton-Bey II received the proposal and notice of opportunity for a hearing on April 8, 2022. Mr. Hampton-Bey II failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Kris A. Hampton-Bey II has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Hampton-Bey II is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Hampton-Bey II is a prohibited act.

Any application by Mr. Hampton-Bey II for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–1322 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *http://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: July 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14899 Filed 7–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–2275]

Determination of Regulatory Review Period for Purposes of Patent Extension; BLENREP

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for BLENREP and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 12, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 9, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted,

such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–E–2275 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; BLENREP.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product BLENREP (belantamab mafodotin-blmf). BLENREP is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. Subsequent to this approval, the USPTO received a patent term restoration application for BLENREP (U.S. Patent No. 9,273,141) from Glaxo Group Ltd, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 1, 2021, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of BLENREP represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BLENREP is 2,352 days. Of this time, 2,107 days occurred during the testing phase of the regulatory review period, while 245 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* February 28, 2014. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 28, 2014.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 5, 2019. FDA has verified the applicant's claim that the biologics license application (BLA) for BLENREP (BLA 761158) was initially submitted on December 5, 2019.

3. *The date the application was approved:* August 5, 2020. FDA has verified the applicant's claim that BLA 761158 was approved on August 5, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 803 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14916 Filed 7–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0115]

Determination That REGLAN Injection (Metoclopramide Injection, USP), Equivalent to 5 Milligrams Base/Milliliter and Equivalent to 10 Milligrams Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that REGLAN Injection (metoclopramide injection, USP), equivalent to (EQ) 5 milligrams (mg) base/milliliter (mL) and EQ 10 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–6650, *daniel.gottlieb@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, is the subject of NDA 017862, held by Hikma Pharmaceuticals USA Inc., and initially approved on February 7, 1979 (EQ 5 mg base/mL) and May 28, 1987 (EQ 10 mg base/mL). REGLAN is indicated for the relief of symptoms associated with acute and recurrent diabetic gastric stasis, prophylaxis of vomiting associated with emetogenic cancer therapy, and prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable. REGLAN may also be used to facilitate small bowel intubation in adults and pediatric patients in whom the tube does not pass the pylorus with conventional maneuvers or to stimulate gastric emptying and intestinal transit of barium in cases where delayed emptying interferes with radiological examination of the stomach and/or small intestine.

REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Baxter Healthcare Corp. submitted a citizen petition dated February 1, 2022 (Docket No. FDA–2022–P–0115), under 21 CFR 10.30, requesting that the Agency determine whether REGLAN Injection (metoclopramide injection, USP), 5 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the EQ 10 mg base/mL strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have